

**IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA**

MAUREEN PIEKANSKI

Plaintiff,

v.

ALEX AZAR II, in his official capacity
as the Secretary of the Department of
Health and Human Services.

Defendant.

Case No. 3:20-cv-00687

(Hon. Martin Carlson)

Electronically Filed

PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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I. INTRODUCTION

The Secretary moved to dismiss Mrs. Piekanski's effort to ensure coverage of her life-saving Tumor Treatment Field Therapy (TTFT) device based on Mrs. Piekanski's purported lack of standing. For the reasons stated below, Mrs. Piekanski's case (seeking coverage of a device that the Secretary has covered four times previously) should not be dismissed.

II. THE PLAINTIFF HAS STANDING

The Secretary contends that this action should be dismissed, purportedly because Mrs. Piekanski lacks standing as ALJ Glaze did not find Mrs. Piekanski liable for the cost of the device under the Medicare program. *See* Dkt. 35 at 8. Even if Mrs. Piekanski were to suffer no economic injury, Mrs. Piekanski has standing because she has been denied her statutory right to Medicare benefits and that, in and of itself, confers an injury. Further, Mrs. Piekanski also suffered injury because, if the denial is not reversed, Mrs. Piekanski could be made personally liable for future claims or, worse, have her access to brain cancer treatment conditioned on personal liability. The Secretary's arguments are without merit.

As described by the Supreme Court in *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), the constitutional minimum of standing has three requirements. First, plaintiff must have suffered an injury in fact, *i.e.*, an invasion of a legally protected interest, which is (a) concrete and particularized; and (b) actual or

imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of. Third, it must be likely that the injury will be redressed by a favorable decision. *Id.* at 560.

Congress may create a statutory right or entitlement, the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially cognizable injury in the absence of the statute. *See Warth v. Seldin*, 422 U.S. 490, 514 (1975). That is, with respect to certain statutes, the alleged violation of a substantive statutorily created right is, alone, a sufficient injury in fact to give rise to Article III standing. *See Linda R.S. v. Richard D.*, 410 U.S. 614, 617 n. 3 (1973) (“Congress may enact statutes creating legal rights, the invasion of which creates standing, even though no injury would exist without the statute.”). Thus, in these circumstances, monetary injury is not the touchstone of standing. Rather, it is the denial of a substantive statutory right.

There can hardly be a doubt that Medicare benefits are an entitlement created by Congress, the denial of which confers standing. *See* 42 U.S.C. § 405(g) (“Any individual ... may obtain a review of such decision”); 42 U.S.C. § 1395ff(a)(1)(A) (“whether an individual is entitled to benefits”); *Heckler v. Ringer*, 466 U.S. 602, 620 (1984) (“the Medicare Act provides both the substance and the standing for [the plaintiff’s] claim”). Thus, because Mrs. Piekanski has been denied her Congressionally created entitlement to Medicare coverage, she has

suffered an injury, and that injury can be redressed by a decision ordering coverage.

The Secretary confusingly argues in his motion that the “statutory right” at issue is Mrs. Piekanski’s procedural right to file suit. *See* Dkt. 35 at 11 (“Plaintiff has exercised her right to file under section 405(g), and there is no allegation that the Secretary interfered with her ability to file this lawsuit. Accordingly, there is no statutory violation, much less a concrete injury.”). At no point did Mrs. Piekanski argue that the Secretary violated a procedural right to file a suit. As noted above, the substantive statutory right that confers standing in this case is the denial of her entitlement to Medicare benefits. Mrs. Piekanski has standing.

The Secretary’s claims regarding an alleged lack of economic injury (Dkt. 35 at 10, 15) do not change the analysis. Multiple courts have rejected the notion that economic injury is a requirement for standing in Medicare claim denial cases. *See, e.g., Ryan v. Burwell*, 2015 WL 4545806 at *5-7 (D. Vt. July 27, 2015) (plaintiff had standing even though Medicaid paid claims denied by Medicare); *Anderson v. Sebelius*, 2010 WL 4273238 at *3 (D. Vt. Oct. 25, 2010) (although administrative law judge waived plaintiff’s financial liability for services delivered, plaintiff still had standing); *Longobardi v. Bowen*, 1988 WL 235576 at *2 (D. Conn. Oct. 25, 1988) (plaintiff had standing even though Medicaid paid claims denied by Medicare); *Martinez v. Bowen*, 655 F.Supp. 95, 99 (D. New

Mexico 1986) (same).

The Secretary's effort to rely on the Supreme Court's decision in *Spokeo, Inc. v. Robins*, 136 S.Ct 1540 (2016) is misplaced. As detailed in *Spokeo*, the mere violation of a "procedural right" *may* not be sufficient to confer standing. *Id.* at 1549. That said, there is a difference between a "procedural right" and a "substantive right." As cogently explained by one court:

A "procedural right" is defined as "a right that derives from legal or administrative procedure; a right that helps in the protection or enforcement of a substantive right." In contrast, a "substantive right" is "a right that can be protected or enforced by law; a right of substance rather than form."

See Bock v. Pressler & Pressler, LLP, 254 F.Supp.3d 724, 732 (D.N.J. 2017) (internal citations and quotations omitted). Here, as set forth in the Complaint, Mrs. Piekanski alleges a violation of her substantive right to payment of her Medicare claim. That the Secretary asserts that someone other than Medicare should bear the expense of the claim does not change the violation of Mrs. Piekanski's substantive right to Medicare payment. Thus, again, Mrs. Piekanski has standing.

Beyond the denial of her substantive statutory rights, it is not correct to say that Mrs. Piekanski will suffer no injury if the claim denial is not reversed. *See* Dkt. 35 at 13. As the *Ryan* and *Anderson* courts recognized, a decision denying coverage that stands unchallenged has significant effects on financial liability for

subsequent claims for coverage. Pursuant to 42 U.S.C. § 1395pp(b) and (c), if a claim is denied and not reversed, then on subsequent claims, the beneficiary may be personally liable. *See also* 42 C.F.R. § 411.404(b). Indeed, administrative law judges have so held with regard to other beneficiaries. *See Exhibit A* attached hereto.

Stated differently, the present harm to Mrs. Piekanski is her being charged with the knowledge of a denial that may be used to create liability on future claims. That this is a present harm is illustrated by the fact that, unless reversed now, Mrs. Piekanski would have no avenue to challenge the denial in this case when considered in a future case. Thus, for example, if a future claim by Mrs. Piekanski is denied, she may be personally liable under 42 U.S.C. § 1395pp because of the denial in this case and, in that future case, Mrs. Piekanski would not be able to challenge the correctness of the decision in this case. This is a present harm. Considered differently, Mrs. Piekanski suffers “the risk of real harm” and, therefore, has standing. *Spokeo*, 136 S.Ct. at 1549.

In this case, as in *Ryan*, Mrs. Piekanski suffers from a chronic/incurable condition and will need tumor treatment field therapy (TTFT) treatment for the remainder of her life. That Mrs. Piekanski will have subsequent claims is, therefore, not speculative. Being subjected to personal liability is an obvious harm of the decision denying Mrs. Piekanski coverage that can be remedied by this

Court. The notice of personal liability that would come from a denial of these claims is not an action “independent” of the Secretary. *See* Dkt. 35 at 15. Rather, it is the direct result of a denial by the Secretary, pursuant to the Medicare Act and regulations.

In addition to its direct impact on Mrs. Piekanski, a consequence of a denial would be to put the supplier (Novocure, Inc.) on notice of potential noncoverage. Thus, if Novocure did not want to be liable for Mrs. Piekanski’s future treatment, it would need to have Mrs. Piekanski sign an ABN. Unless the decision is reversed, Mrs. Piekanski may be put to the choice of financially harming her family by receiving life-extending care or foregoing treatment and markedly reducing her chances of extra months or years of life. That is a choice Mrs. Piekanski should not be forced to make; and it can be avoided altogether if the challenged decision is reversed.

The Secretary concludes his argument by stating that Mrs. Piekanski cannot fulfill the third element of standing because a “hypothetical billing dispute” between Mrs. Piekanski and the supplier could occur after a favorable decision was rendered. Dkt. 35 at 15-16. Respectfully, the Secretary’s argument is difficult to follow. At base, the Secretary’s conjecture that a theoretical change in the supplier’s billing practices could somehow undermine a favorable decision on coverage is nonsensical. A favorable decision would result in Medicare’s

reimbursement of the claims at issue, and notice of non-coverage would be avoided. If the Secretary's decision of non-coverage is overturned, Mrs. Piekanski will have a remedy for her injury.

III. CONCLUSION

The Secretary's Motion to Dismiss should be denied.

Respectfully submitted,

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